PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

# PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

| | |
|---|---|
| **Date of mailing** (day/month/year)<br>22 December 2000 (22.12.00) | |
| **International application No.**<br>PCT/SE00/00573 | **Applicant's or agent's file reference**<br>99 P 2006 P |
| **International filing date** (day/month/year)<br>23 March 2000 (23.03.00) | **Priority date** (day/month/year)<br>31 March 1999 (31.03.99) |
| **Applicant**<br>MIN, Mart et al | |

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

24 August 2000 (24.08.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

| | |
|---|---|
| **The International Bureau of WIPO**<br>**34, chemin des Colombettes**<br>**1211 Geneva 20, Switzerland** | Authorized officer<br>C. Cupello |
| Facsimile No.: (41-22) 740.14.35 | Telephone No.: (41-22) 338.83.38 |

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

# PCT

## NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

ST. JUDE MEDICAL AB
Patent Department
S-175 84 Järfälla
SUÈDE

**Date of mailing** (day/month/year)
23 November 2000 (23.11.00)

**Applicant's or agent's file reference**
99 P 2006 P

**IMPORTANT NOTIFICATION**

**International application No.**
PCT/SE00/00573

**International filing date** (day/month/year)
23 March 2000 (23.03.00)

1. The following indications appeared on record concerning:

[X] the applicant [ ] the inventor [ ] the agent [ ] the common representative

Name and Address
PACESETTER AB
S-175 84 Järfälla
Sweden

State of Nationality: SE
State of Residence: SE
Telephone No.:
Facsimile No.:
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [X] the name [ ] the address [ ] the nationality [ ] the residence

Name and Address
ST. JUDE MEDICAL AB
S-175 84 Järfälla
Sweden

State of Nationality: SE
State of Residence: SE
Telephone No.:
Facsimile No.:
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[ ] the International Preliminary Examining Authority
[X] the designated Offices concerned
[ ] the elected Offices concerned
[ ] other:

**The International Bureau of WIPO**
**34, chemin des Colombettes**
**1211 Geneva 20, Switzerland**
Facsimile No.: (41-22) 740.14.35

Authorized officer
C. Cupello
Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY



# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
|---|---|---|
| 99 P 2006 P | | |
| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
| PCT/SE00/00573 | 23/03/2000 | 31/03/1999 |
| International Patent Classification (IPC) or national classification and IPC<br>A61N1/365 | | |
| Applicant<br>ST. JUDE MEDICAL AB et al. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 24/08/2000 | 05.07.2001 |
| Name and mailing address of the international preliminary examining authority:<br>European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465 | Authorized officer<br>Wetzig, T<br>Telephone No. +49 89 2399 7412 |

Form PCT/IPEA/409 (cover sheet) (January 1994)

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/SE00/00573

## I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
**Description, pages:**

| | | |
|---|---|---|
| 1,4-10 | as published | |
| 2,3 | with telefax of | 04/04/2001 |

**Claims, No.:**

| | | |
|---|---|---|
| 1-9 | with telefax of | 04/04/2001 |

**Drawings, sheets:**

| | |
|---|---|
| 1/3-3/3 | as published |

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   *(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 1-9 |
| | No: | Claims | |
| Inventive step (IS) | Yes: | Claims | 1-9 |
| | No: | Claims | |
| Industrial applicability (IA) | Yes: | Claims | 1-9 |
| | No: | Claims | |

2. Citations and explanations
   **see separate sheet**

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:
**see separate sheet**

1. In this report reference is made to the following documents:

   D1....EP-A-0 879 618
   D2....US-A-5 305 745

ad V:

1.1. Document D1, which is considered to represent the most relevant prior art, discloses a rate adaptive pacemaker comprising a pacing rate limiting means for preventing the pacing rate from becoming too high. The pacing rate limiting means is adapted to limit the pacing rate upwards such that a predetermined relation between supplied and consumed energy is maintained. The pacing rate limiting means comprises a corresponding upper limit determining means.

Claim 1 differs in the following:

The pacing rate limiting means is adapted to limit the pacing rate upwards such that the energy consumed by the myocardium **always** is **less** than the energy supplied to the myocardium.

The device disclosed in document D1 lowers the upper pacing rate limit **in response** to an ischemia, that means in response to a situation in which the energy consumed by the myocardium is **higher** than the energy supplied to the myocardium. Consequently, the pacing rate limiting means of the device disclosed in document D1 is not able to limit the pacing rate upwards such that the energy consumed by the myocardium **always** is **less** than the energy supplied to the myocardium.

Document D2 does not disclose a device comprising an upper rate limiting means which is adapted to limit the pacing rate upwards such that the energy consumed by the myocardium always is less than the energy supplied to the myocardium.

Therefore, the subject-matter of claim 1 is considered as novel (Article 33(2) PCT).

1.2. The subject-matter of claim 1 is considered as involving an inventive step (Article

33(3) PCT) for the following reasons:

In the pacemaker defined in claim 1, the pacing rate can be limited upwards under avoidance of ischemia, and thus, the patient can feel more healthy and comfortable in various everyday life conditions.

1.3. Claims 2-9 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

ad VII:

1. To meet the requirements of Rule 6.2(b) PCT, in claim 2, the reference sign "14" should have been added to the term "pacing rate limiting means".

PCT

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International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61N 1/365

A1

(11) International Publication Number: WO 00/57954

(43) International Publication Date: 5 October 2000 (05.10.00)

(21) International Application Number: PCT/SE00/00573

(22) International Filing Date: 23 March 2000 (23.03.00)

(30) Priority Data:
9901195-9 31 March 1999 (31.03.99) SE

(71) Applicant *(for all designated States except US)*: PACESETTER AB [SE/SE]; S-175 84 Järfälla (SE).

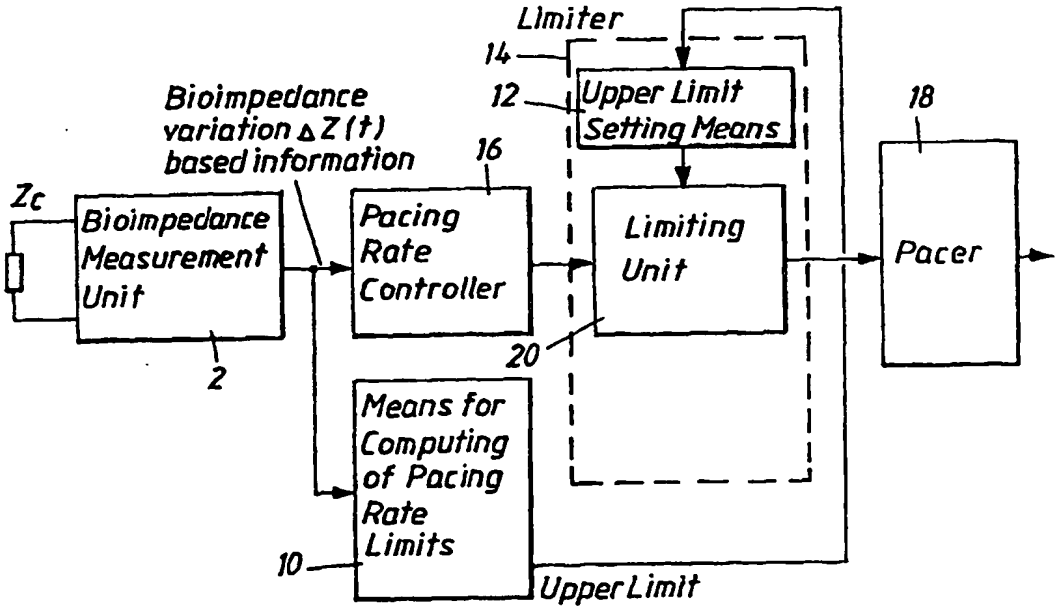
(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: MIN, Mart [EE/EE]; Söpruse pst 188A-4, EE13424 Tallinn (EE). KINK, Andres [EE/EE]; Nabala tee 2A, EE75401 Harjumaa (EE). PARVE, Toomas [EE/EE]; Rännaku blvd. 3-7, EE10917 Tallinn (EE).

(74) Common Representative: PACESETTER AB; Patent Department, Kalling, Sven, S-175 84 Järfälla (SE).

(81) Designated States: US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

**Published**
*With international search report.*
*Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.*

(54) Title: A RATE ADAPTIVE PACEMAKER




(57) Abstract

A rate adaptive pacemaker comprises means (2) for determining the demand of a patient's organism, a pacing rate controlling means (16) for controlling the pacing rate in response to the patient's demand, and a pacing rate limiting means (20) for preventing the pacing rate from becoming too high. The pacing rate limiting means is adapted to limit the pacing rate upwards such that a predetermined relation is maintained between energy supplied to the myocardium and energy consumed by the myocardium.

*FOR THE PURPOSES OF INFORMATION ONLY*

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

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| **EE** | Estonia | **LR** | Liberia | **SG** | Singapore | | |

The purpose of the present invention is to propose a new way of continuously automatically limiting the pacing rate upwards according to the current ability of the patient's heart.

Disclosure of the Invention

This purpuse is obtained by a rate adaptive pacemaker according to claim 1.

Thus, in the pacemaker according to the invention the myocardium energy consumption and energy supply can be kept in balance, and since this relation, and not the heart rate, is of primary importance, the patient can feel more healthy and comfortable in various everyday life conditions, also in conditions of active work.

Preferred embodiments are set forth in the dependent claims.

According to an advantageous embodiment of the pacemaker according to the invention the pacing rate limiting means is adapted to limit the pacing rate upwards such that the energy consumed by the myocardium always is less than the energy supplied to the myocardium. In this way lack of oxygen supply to the myocardium is avoided.

According to another advantageous embodiment of the pacemaker according to the invention said pacing rate limiting means includes an upper limit setting means for setting an upper limit value for the pacing rate, and an upper limit determining means to determine the relation between energy supplied to the myocardium and energy consumed by the myocardium for calculating an upper pacing rate limit value from said relation for supply to said upper limit setting means. Thus, in this way the actual pacing rate is continuously compared to a set upper limit value and the actual pacing rate is limited to a maximum value equal to this limit value.

According to still other advantageous embodiments of the pacemaker according to the invention said pacing rate limiting means is adapted to limit the pacing rate such that the inequality

$$(t_{diast,rest}/t_{diast})\cdot(SV/SV_{rest}) < CR \quad (1)$$

is satisfied, alternatively said upper limit determining means is adapted to determine actual coronary resistance ratio (CRR) from the equation

$$\text{supplied energy} = \text{consumed energy} \quad (2)$$

and determine an upper pacing rate limit from the relation between actual coronary resistance ratio (CRR) and coronary reserve (CR), or said upper limit determining means is adapted to determine the upper pacing rate limit value from the equation

$$\text{upper pacing rate limit} = (60\cdot CR) \,/\, [t_{diast,rest}\cdot(SV/SV_{rest}) + CR\cdot t_{syst}] \quad (3)$$

where $t_{diastrest}$ denotes diastolic duration for the patient in rest conditions, $t_{diast}$ actual diastolic duration for the patient, SV and $SV_{rest}$ actual stroke volume and stroke volume for the patient in rest conditions respectively, and $t_{syst}$ the actual systolic duration. The term "rest condition" is intended to cover not only resting by lying down but also other standard defined low load conditions such as sitting. A bioimpedance measurement unit is preferably provided to measure the intracardiac bioimpedance as a function of time and determine therefrom actual stroke volume SV and actual diastolic and systolic duration $t_{diast}$ and $t_{syst}$ respectively. Since the electrical bioimpedance can be effectively used to determine cardiac parameters, in particular the parameters mentioned above can be obtained from the time variation of the bioimpedance measured between the tip of an intracardiac electrode and the housing of a pacemaker when an exitation

*Claims*

1. A rate adaptive pacemaker comprising a means (2) for determining the demand of a patient's organism, a pacing rate controlling means (16) for controlling the pacing rate in response to the patient's demand, and a pacing rate limiting means (20) for preventing the pacing rate from becoming too high, **characterized in** that said pacing rate limiting means (14) is adapted to limit the pacing rate upwards such that a predetermined relation is maintained between energy supplied to the myocardium and energy consumed by the myocardium.

2. The pacemaker according to claim 1, **characterized in** that said pacing rate limiting means is adapted to limit the pacing rate upwards such that the energy consumed by the myocardium always is less than energy supplied to the myocardium.

3. The pacemaker according to claims 1 or 2, **characterized in** that said pacing rate limiting means is adapted to limit the pacing rate such that the inequality

$$(t_{diast,rest}/t_{diast})\cdot(SV/SV_{rest}) < CR$$

is satisfied, where $t_{diastrest}$ denotes diastolic duration for the patient in rest conditions, $t_{diast}$ actual diastolic duration for the patient, SV and $SV_{rest}$ actual stroke volume and stroke volume for the patient in rest conditions respectively, and CR the coronary reserve.

4. The pacemaker according to any of the preceding claims, **characterized in** that said pacing rate limiting means includes an upper limit setting means for setting an upper limit value for the pacing rate, and an upper limit determining means for determining the relation between energy supplied to the myocardium and energy consumed by the myocardium for calculating an upper pacing rate limit value from said relation for supply to said upper limit setting means.

5. The pacemaker according to claim 4, **characterized in** that said upper limit determining means includes an energy determining means for determining the energy supplied to the myocardium and the energy consumed by the myocardium respectively, and a comparison means for comparing supplied energy and consumed energy for determining said relation.

6. The pacemaker according to claim 5, **characterized in** that said energy determining means is adapted to determine consumed energy as the product of mean value of ventricular pressure variations during a cardiac cycle and stroke volume.

7. The pacemaker according to claims 5 or 6, **characterized in** that said energy determining means is adapted to determine supplied energy from the time response curve of the arterial pressure during diastole.

8. The pacemaker according to claim 4, **characterized in** that said upper limit determining means is adapted to determine actual coronary resistance ratio (CRR) from the equation

supplied energy = consumed energy

and determine an upper pacing rate limit value from the relation between actual coronary resistance ratio (CRR) and coronary reserve (CR).

9. The pacemaker according to any of the claims 4 - 8, **characterized in** that said upper limit determining means is adapted to determine the upper pacing rate limit value from the equation

$$\text{upper pacing rate limit} = (60 \cdot CR)/[t_{diast.rest} \cdot (SV/SV_{rest}) + CR \cdot t_{syst}]$$

where CR denotes the coronary reserve, $t_{diastrest}$ diastolic duration for the patient in rest conditions, SV and $SV_{rest}$ actual stroke volume and stroke volume for the patient in rest conditions respectively, and $t_{syst}$ the actual systolic duration.

10. The pacemaker according to any of the claims 3 - 9, **characterized in** that a bioimpedance measurement unit is provided to measure the intracardiac bioimpedance as a function of time and determine therefrom actual stroke volume

SV and actual diastolic or systolic durations $t_{diast}$ or $t_{syst}$ respectively.

11. The pacemaker according to any of the claims 3 - 9, **characterized in** that an ECG measuring and analyzing unit is provided to measure ECG and determine therefrom actual stroke volume SV and actual diastolic or systolic durations $t_{diast}$ or $t_{syst}$ respectively.

Fig. 1a

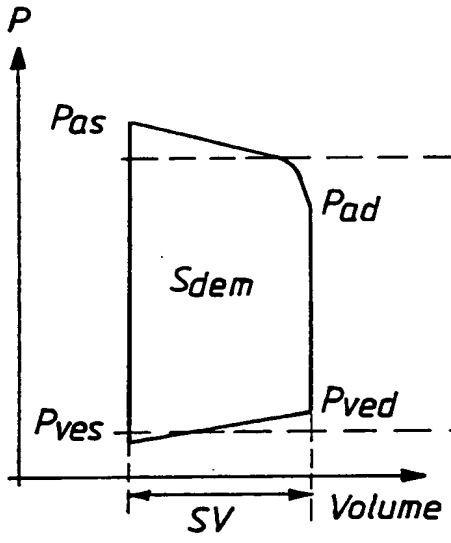



Fig. 1b

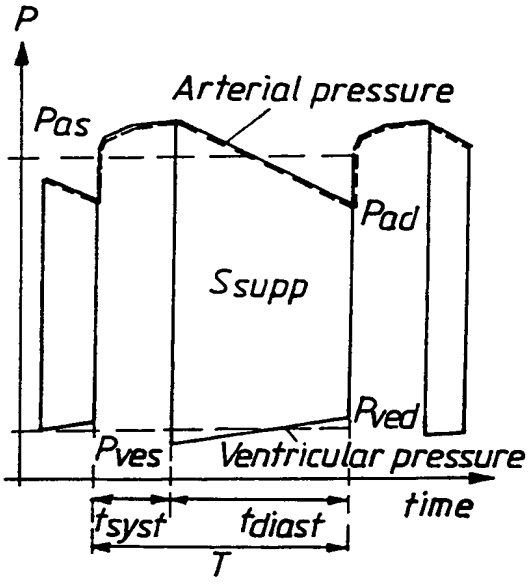



Fig. 2a

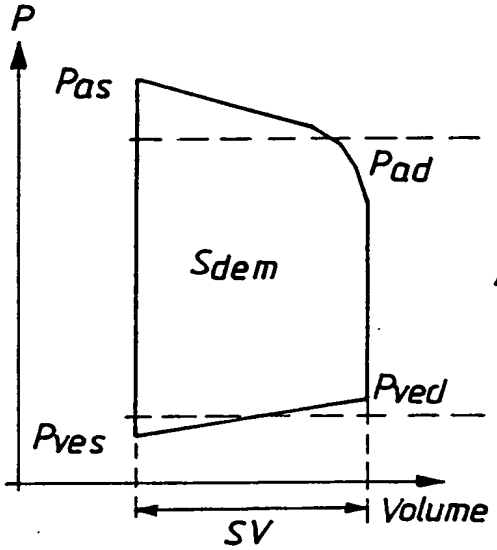



Fig. 2b

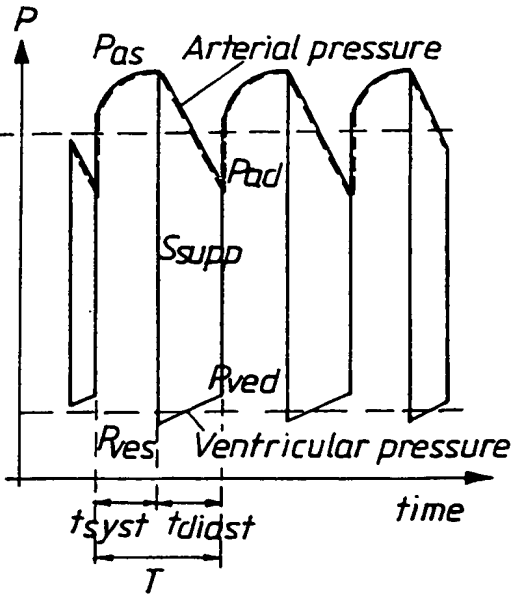


Fig. 3

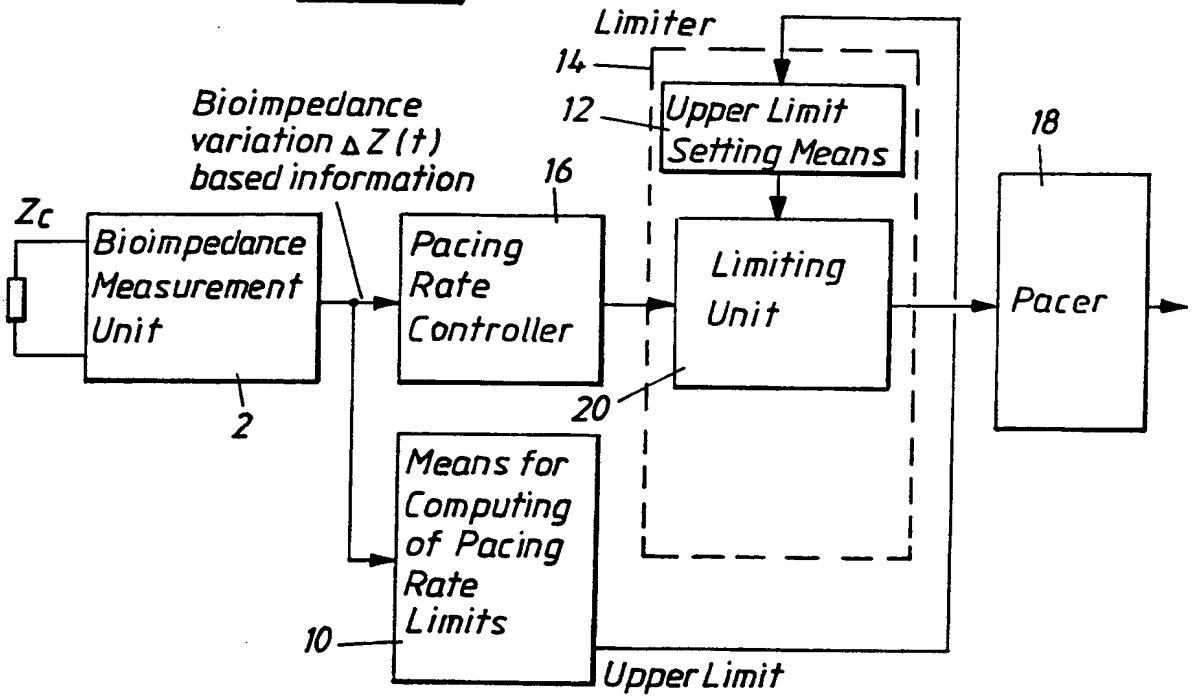

Limiter
14
12
Upper Limit Setting Means
18
Bioimpedance variation Δ Z (t) based information
16
Zc
Bioimpedance Measurement Unit
Pacing Rate Controller
Limiting Unit
Pacer
2
20
Means for Computing of Pacing Rate Limits
10
Upper Limit

Fig. 4

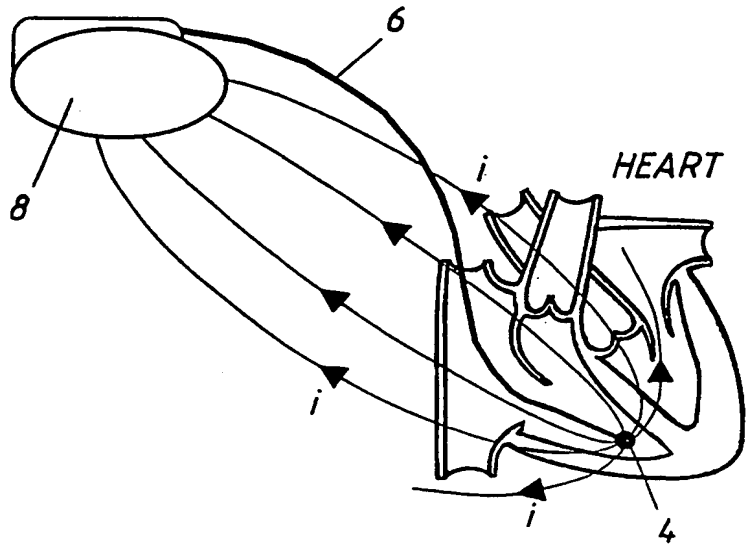
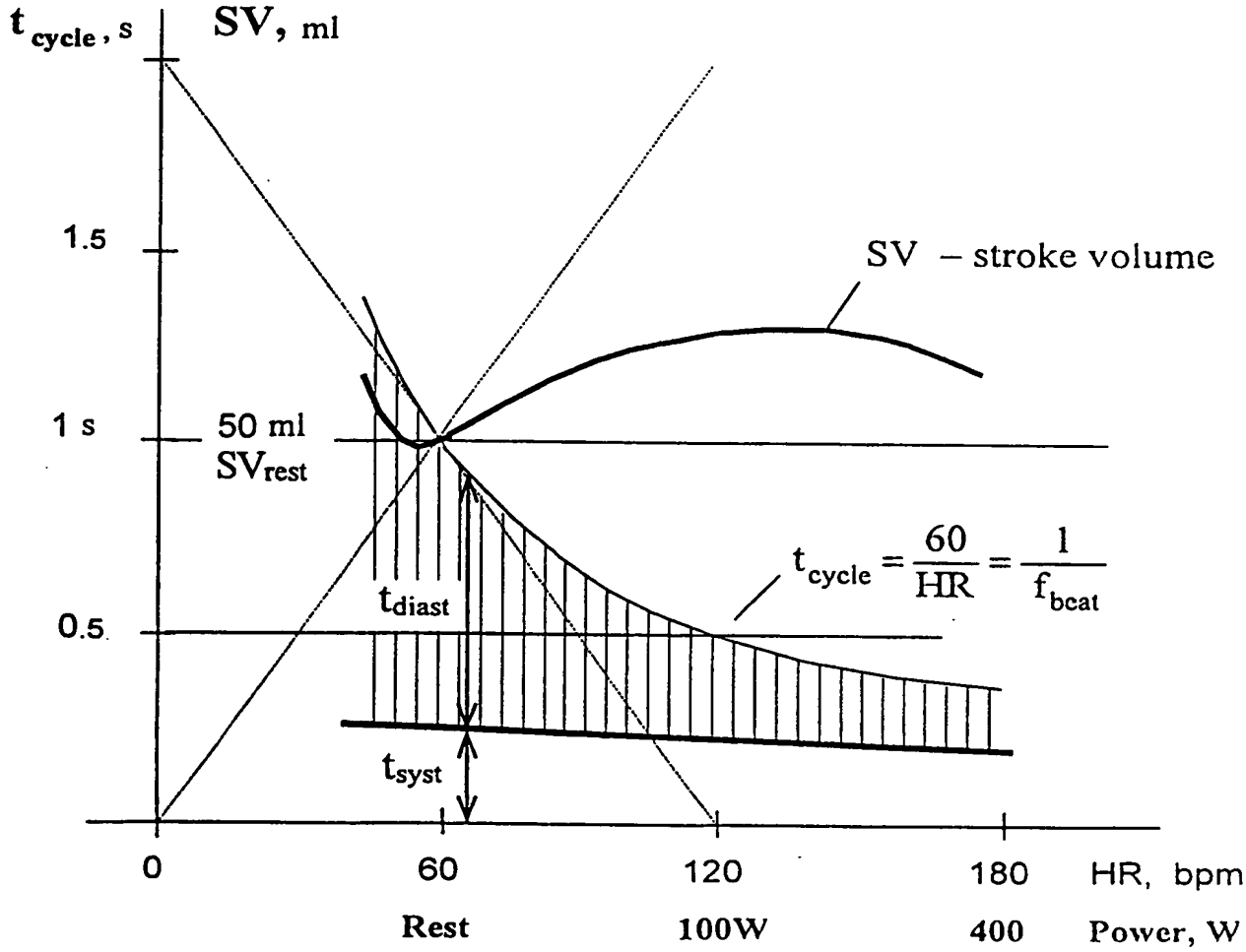

6
8
i
HEART
i
i
4

Fig.5


$t_{cycle}$, s
SV, ml
1.5
1 s
0.5
50 ml
$SV_{rest}$
SV – stroke volume
$t_{cycle} = \frac{60}{HR} = \frac{1}{f_{beat}}$
$t_{diast}$
$t_{syst}$
0
60
120
180
HR, bpm
Rest
100W
400
Power, W

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 00/00573

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/365
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 5305745 A (FRED ZACOUTO), 26 April 1994 (26.04.94), column 40, line 24 - column 41, line 63 | 1,2,4,5,10 |
| D,A | EP 0879618 A1 (PACESETTER AB), 25 November 1998 (25.11.98), abstract | 1-10 |

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 26 June 2000 | 24 -07- 2000 |
| Name and mailing address of the ISA/<br>Swedish Patent Office<br>Box 5055, S-102 42 STOCKHOLM<br>Facsimile No. +46 8 666 02 86 | Authorized officer<br>Nikolaj Hautaviita/Els<br>Telephone No. +46 8 782 25 00 |

Form PCT/ISA/210 (second sheet) (July 1992)

# INTERNATIONAL SEARCH REPORT

Information on patent family members

02/12/99

International application No.
PCT/SE 00/00573

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| US 5305745 A | 26/04/94 | AT 103498 T | 15/04/94 |
| | | CA 1327838 A | 15/03/94 |
| | | DE 68914199 D,T | 14/07/94 |
| | | EP 0348271 A,B | 27/12/89 |
| | | FR 2632533 A,B | 15/12/89 |
| | | FR 2637807 A,B | 20/04/90 |
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